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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,928	07/21/2003	Ulrich Posanski	4-20017F	6463

1095 7590 10/19/2005

NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/623,928		POSANSKI, ULRICH	
	<b>Examiner</b>		<b>Art Unit</b>	
	Blessing M. Fubara		1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 July 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 11-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time and request for reconsideration, both filed 07/29/05. Claims 11-20 are pending.

#### ***Claim Rejections - 35 USC § 103***

1. Claims 11-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hauer et al. (US 5,342,625).

- a. Applicant disagrees that Reggio (cited as a teaching reference) recognizes polyglycerol esters as lipophilic surfactants because according to applicant, Reggio uses the polyglycerol esters as unique plasticizing agent as a chewing gum base as a film for superior bubble blowing character and that the Reggio art is a non-analogous art.
- b. Applicant further argue that there is no suggestion in Hauer to make the claimed invention and Hauer does not provide reasonable expectation of success to make the claimed invention where “cyclosporine (and other therapeutic agents such as rapamycin, tacrolimus, deoxyspergualine, mycophenolate-mofetil, nifedipine, nimodipine, topside or ibuprofen) are contained in a carrier medium comprising sorbitan fatty acid ester having HLB value of less than 10, an oil comprising a triglyceride as essential lipophilic component and non-ionic surfactant having HLB value of greater than 10, in the relative amounts presently claimed.”
- c. Furthermore, applicant does not agree that “one skilled in the art would combine hydrophilic with lipophilic phases in order to render cyclosporine soluble, and select a surfactant from among equally suitable materials” because such a combination would be

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a situation of “obvious to try,” which is not the standard of 35 USC 103(a) (“*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)”).

2. Applicant's arguments filed 07/29/05 have been fully considered but they are not persuasive.

Regarding a.

Reggio was not cited as art in combination with Hauer against the claims. Applicant does not however dispute that polyglycerol esters are lipophilic. Secondly, it is noted that Hauer specifically discloses a carrier composition that comprises hydrophilic phase, lipophilic phase and surfactant (column 6, lines 47-50). Furthermore, Hauer discloses sorbitan fatty acid esters such as SPAN, sorbitan monolauryl ester, sorbitan monmopalmityl ester, sorbitan monostearyl ester, sorbitan tristearyl ester, sorbitan monooleyl ester and sorbitan trioyleyl ester as lipophilic (column 11, lines 7, 8 and 53-58); and these sorbitan fatty acid esters are the same sorbitan fatty acid esters recited in claim 15. Also, the use of the polyglycerol esters in Reggio as plasticizing agent does not preclude the ester from being lipophilic and lipohilicity or hydrophylicity is a property of a material and a material and its property cannot be separated.

3. In response to applicant's argument that Reggio is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the claims are not rejected over Reggio.

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Regarding b.

The active agent of the claims is selected from the group consisting of cyclosporin, ... and ibuprofen and in this case the prior art only has to disclose one of the agents defined by the Markush. Hauer discloses a composition that comprises cyclosporine, hydrophilic phase, lipophilic phase and surfactant (column 6, lines 47-50). Hauer discloses sorbitan fatty acid esters such as SPAN, sorbitan monolauryl ester, sorbitan monomopalmityl ester, sorbitan monostearyl ester, sorbitan tristearyl ester, sorbitan monooleyl ester and sorbitan trioylel ester as lipophilic (column 11, lines 7, 8 and 53-58) and these are lipophilic and meet the limitation of claim 11 a). The lipophilic phase in Hauer contains fatty acid triglycerides such as neutral plant oils and non-hydrogenated vegetable oil (column 8, line 58 to column 9 line 39; column 11, lines 15-17), which meets the limitation of claim 11 b) and those recited in claim 16. The surfactant in Hauer is CREMOPHOR or the TWEEN type surfactants or MYRJ (column 9, line 61; column 10, lines 1, 9-41), which meets the limitation of claim 11 c). Thus Hauer discloses the instant composition. The lipophilic phase is present at 2-45%. Thus in Hauer, there is reasonable expectation of success because, Hauer discloses the claimed invention within the list of surfactants, lipophilic and hydrophilic materials disclosed.

Regarding c).

Although Hauer provides lists of agents that are lipophilic and hydrophilic and surfactant, the Hauer reference discloses the claimed composition. The skilled artisan having the necessary skills to prepare the desired composition from Hauer's disclosure of specific lipophilic, hydrophilic and surfactant is not obvious to try but a prima facie case of obviousness because Hauer discloses the claimed composition.

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No claim is allowed.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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